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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,350	08/24/2000	Klaus Cichutek	11692-004001	3834

7590

05/06/2003

Fish & Richardson
225 Franklin Street
Boston, MA 02110-2804

EXAMINER

WINKLER, ULRIKE

ART UNIT

PAPER NUMBER

1648

20

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/555,350

Applicant(s)

CICHUTEK ET AL.

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 10-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Applicant's election without traverse of Group I (claims 1-9) in Paper No. 19 is acknowledged.

Specification

Applicant is required to update the status (pending, allowed, ect.) of all parent priority applications in the first line of the specification.

Sequence listing

Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 5, is attached to the instant Office Action.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the instant Office Action. Correction is required.

Some of the figures have heavy/dark shading, this does not reproduce well. Applicant is requested to make changes to the figure so that they will clear and easy to read and photocopy.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent specific vector - pTC53 - is required to practice the claimed invention. As such it must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise known and readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by an enabling deposit of the vector – pTC53. Therefore, a deposit at a recognized depository may be made for enablement purposes.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

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- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years. Or 5 years after the last request for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see CFR 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Dornburg (U.S. Pat No. 5,869,331) as evidenced by Novotny et al. (in Molecular Biology and Biotechnology, 1995).

The instant invention is drawn to a cell-specific retroviral vector, comprising the steps of making a single chain antibody (steps a-g) against a cell surface receptor (immunizing animal with cell population) the single chain antibody encoding DNA is then inserted into a psi-negative retroviral expression vector. The retroviral Env expression vector is from spleen necrosis virus (SNV).

Dornburg discloses a retroviral vector particles having target cell specificity which comprises a retroviral vector having a targeting peptide fused to the envelope protein of the retroviral vector to form a targeting envelope. The targeting peptide replaces or disrupts the

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natural viral receptor binding site and the targeting peptide is a peptide that specifically binds a specific receptor of the target cell (see abstract). To alter the host range of a vector particle, retroviral vector particles may be constructed that contain modified envelope proteins that recognize only a cell surface structure (receptor) specific for the target cell of interest. Proteins known to recognize specific structures of proteins are antibody molecules. Hence, to make a retroviral vector particle specific for a cell-type of interest, the viral receptor binding peptide may be replaced with an antigen binding site of an antibody molecule (see column 4, lines 25-34). To construct a targeting envelope containing the antigen binding site of an antibody directed against a cell-surface protein expressed on several human tumor cells, the corresponding single chain antibody gene (termed B6.2) made for expression in *E. coli*. was modified in the following way: PCR technology was used to amplify the B6.2 scA gene using the original *E. coli*. expression plasmid as template (see column 7, lines 31-35). Helper cells are made by the transfection of plasmids expressing all retroviral proteins necessary to form infectious virus particles. One plasmid is designed to express all core/proteins (expression of gag and pol). The other plasmid is designed to express the envelope precursor/protein. Both plasmid constructs do not contain retroviral cis/acting sequences for virus replication (e.g., encapsidation sequences, a primer binding site etc.) (see column 13, lines 5-30). Plasmids expressing mutant envelope genes of spleen necrosis virus (SNV) are used in the process (see column 13, lines 34-50). The production of antibodies to cell surface receptors is well known to require the injection of cells into an animal. The production of single chain antibodies has become a standard technique in the art (see Novotny et al. in *Molecular Biology and Biotechnology*, 1995, specifically figure 7). Therefore, the instant invention is rejected over Dornburg.

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Conclusion

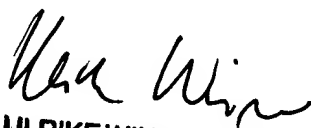
No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ULRIKE WINKLER, PH.D. 5/5/03
PATENT EXAMINER